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TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
INE-0061

In Re Application Of: Shikhman et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/037,899	10/22/01	Jessica Baxter	23413	3731	6867

Invention: CRIMPING AND CUTTING DEVICE

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

☒ Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

- ☐ A check in the amount of the fee is enclosed.
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Signature

Dated: 8/16/05

H.M. BEDINGFIELD
REG. NO. 44,530
CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002
860.286.2929

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H.M. BEDINGFIELD

Typed or Printed Name of Person Mailing Correspondence

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Oleg Shikhman et al)
SERIAL NUMBER: 10/037,899) Group Art Unit: 3731
FILED: October 22, 2001) Before the Examiner:
FOR: CRIMPING AND CUTTING DEVICE) Jessica Baxter

APPEAL BRIEF

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(1) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(2) REAL PARTY IN INTEREST

The real party in interest is Interventional Therapies.

(3) HISTORY OF THE PROSECUTION

The application was filed on October 22, 2001 with 64 claims. An election of species requirement was issued on July 23, 2005. Claims 15-54 and 60-64 were withdrawn from consideration pursuant to the election of species requirement on November 25, 2003. A first action on the merits was mailed December 17, 2003. Claims 1 and 55 were amended on June 17, 2004 in a response to the first action on the merits. A final action on the merits was filed by the Examiner on September 17, 2004. A notice of appeal was filed March 16, 2005. The present appeal is pursuant to a final rejection of claims 1-14 and 55-59, dated September 17, 2004.

(4) STATUS OF THE CLAIMS

The application was filed on October 22, 2001 with 64 claims. Claims 15-54 and 60-64 were withdrawn from consideration pursuant to an election of species requirement dated July 25, 2003. Claims 1 and 55 were amended on June 17, 2004. The present appeal is pursuant to a final rejection of claims 1-14 and 55-59, dated September 17, 2004. A copy of the claims as amended is attached hereto at Appendix I.

(5) GROUPING OF THE CLAIMS

The claims do not stand or fall together in so much as independent claims 1 and 55 are argued separately.

(6) SUMMARY

The presently pending claims relate to crimping and cutting device having a tip, a ferrule received in the device tip, which ferrule itself receives suture material, a hammer head configured to crimp the ferrule received in the device tip, and a generally stationary cutting edge in the device tip.

Reference is made to Figures 26-29, which shows an exemplary embodiment in accordance with the claims. The device tip is represented by 40. The hammer is 24, having a hammer head 112. The ferrule 42 is received in the tip 40 and crimps the ferrule 42. Finally, the generally stationary cutting edge 144 effects cutting of the suture 170. A thorough description of this exemplary process appears in the Applicant's specification at page 13, line 24 to page 14, line 22.

For the convenience of the Examiner and the Board, independent claims 1 and 55 are reproduced hereinbelow:

1. (Once amended) A crimping and cutting device comprising:

a hammer head having a first side and an opposite second side, and a ferrule engaging edge located on the second side;

a tip having a distal end and a proximal end, the tip having a hammer head opening for receiving the hammer head, the hammer head opening extending from the distal end of the tip to the proximal end of the tip, the tip further having a ferrule accepting opening near the distal end of the tip, and a generally stationary cutting edge within the hammer head opening, the cutting edge located proximally of the ferrule accepting opening.

55. (Once amended) A method of securing suture material using a crimping and cutting device, the method comprising:

threading the suture material through a ferrule in the device;

moving a hammer head proximally through a tip of the device to crimp the ferrule;

continuing to move the hammer head proximally after the ferrule has been crimped entrapping the suture material within the ferrule;

abutting the hammer head against a generally stationary cutting edge within the tip, capturing the suture material therebetween; and,

applying pressure with the hammer head against the cutting edge until the suture material is cut.

(7) ISSUES ON APPEAL

- (A) Claims 1-3, 5-8, 10, 12-14, 55-56 and 58-59 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,643,289 to Sauer et al. (hereinafter "Sauer '289").
- (B) Claims 1-10, 12 and 55-56 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,641,592 to Sauer et al. (hereinafter "Sauer '592").
- (C) Claims 11 and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer '289 in view of U.S. Patent No. 5,839,639 to Sauer et al. (hereinafter "Sauer '639").

(8) DISCUSSION

A. *With regard to the rejections of claims 1-3, 5-8, 10, 12-14, 55-56 and 58-59 under 35 U.S.C. 102(b) as being anticipated by Sauer '289:*

It is noted that a number of features of the claims are evidently lacking from the Sauer '289 reference. With specific regard to independent claim 1 and independent claim 55, the '289 reference fails to describe a generally stationary cutting edge. Indeed, with regard to Figures 7-9 of the '289 reference, the cutting edge of Sauer '289 extends a significant distance distally to cut the suture following crimping of the ferrule 100 by the hammer 26. (Note: the Examiner contends that because the motion is "limited in motion," it is generally stationary. By this, any object with at least some limitation on directional movement would be generally stationary (e.g., a bullet train would be generally stationary because it cannot move laterally off the tracks), and the only non-stationary particles would be free particles).

As is well known, in order to anticipate a reference, the cited reference must teach or suggest every limitation of the claims (so called "all elements rule"). Because this limitation is not taught or suggested by the '289 reference, the rejections of claims 1-3, 5-8, 10, 12-14, 55-56 and 58-59 under 35 U.S.C. 102(b) are improper.

Further with regard to independent claim 1, even if the cutting blade of Sauer '289 is "generally stationary" as the Examiner contends in the Office Action dated September 17, 2004, then the cutting edge would not be located proximally of the ferrule accepting opening, as is required by claim 1. When the blade of Sauer '289 actually cuts the suture, it is certainly more distal of the opening than proximal (the finishing stroke is into an indentation on the distal side of the opening (See Fig. 9)). Again, the rejections are improper.

With further regard to independent claim 55, the hammer head is certainly not moved proximally to crimp the ferrule. Again, with reference to Figures 7-9, the hammer 26 is moved distally against the ferrule 100. Because this limitation is lacking, the rejections of claims 55-56 and 58-59 are improper.

There is no teaching to abut the hammer head 26 of Sauer '289 (via proximal movement of the hammer 26 or otherwise) against a cutting edge (generally stationary or not) to cut suture. Because this limitation is lacking, the rejections are improper.

B. *With regard to the rejections of Claims 1-10, 12 and 55-56 under 35 U.S.C. 102(e) as being anticipated by Sauer '592:*

Sauer '592 also fails to teach every limitation of independent claims 1 and 55. Specifically, Sauer '592 fails to teach the generally stationary cutting edge within the hammer head opening. Rather, like Sauer '289, Sauer '592 teaches a movable cutting blade (thus a movable cutting edge; See Figs 16 B-E in Sauer '592). As noted above, the Examiner contends that any limitation on movement of an object renders that object "generally stationary." Above, we noted that by that argument, the Examiner might count a bullet train as being "generally stationary" because it cannot move laterally off of the tracks (the flaws in this argument are apparent). Because the '592 has somewhat more rotational motion, we might instead say that the Examiner would contend that the tip of a baseball bat in a baseball swing is "generally stationary" because it does not travel in a linear fashion.

Because the Sauer '592 reference does not teach or suggest a generally stationary cutting edge, the rejections of claims 1-10, 12 and 55-56 under 35 U.S.C. 102(e) are improper.

C. *With regard to the rejections of claims 11 and 57 under 35 U.S.C. 103(a) as being unpatentable over Sauer '289 in view of Sauer '639:*

The Sauer '639 patent is directed to a collapsible anvil assembly for a stapler, and is presented by the Examiner merely as evidence that "safety buttons" are known as devices which may prevent premature firing of devices. The Sauer '639 patent does not otherwise add, and the Examiner does not assert that the Sauer '639 patent otherwise adds, to the teachings of the '289 patent to approximate claims 1 or 55 or to make up for the deficiencies of the '289 patent with regard to the independent claims. Accordingly, a prima facie case of obviousness is not made out for even those independent claims, much less the rejected dependent claims 11 and 57. For this reason, the rejections are improper and should be withdrawn.

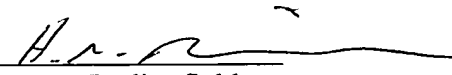
(9) CONCLUSION

The rejections are in error and should be withdrawn.

If there are any charges with respect to the presently submitted response or otherwise, please charge them to deposit account 06-1130, maintained by the Applicant's attorneys.

Respectfully Submitted,

CANTOR COLBURN, LLP
Applicant's Attorneys

By: 
H. M. Bedingfield
Registration No. 44,530

Dated: August 16, 2005
Address: 55 Griffin Road South, Bloomfield, CT 06002
Telephone: (860) 286-2929

APPENDIX I

1. (Once amended) A crimping and cutting device comprising:

a hammer head having a first side and an opposite second side, and a ferrule engaging edge located on the second side;

a tip having a distal end and a proximal end, the tip having a hammer head opening for receiving the hammer head, the hammer head opening extending from the distal end of the tip to the proximal end of the tip, the tip further having a ferrule accepting opening near the distal end of the tip, and a generally stationary cutting edge within the hammer head opening, the cutting edge located proximally of the ferrule accepting opening.

2. (original) The crimping and cutting device of claim 1 wherein the hammer head further comprises a first camming surface located on the first side of the hammer head and the tip comprises a second camming surface near the distal end of the tip and opposite the ferrule accepting opening.

3. (original) The crimping and cutting device of claim 2 wherein movement of the hammer head in a proximal direction directs the hammer head towards the ferrule accepting opening.

4. (original) The crimping and cutting device of claim 2 wherein the second camming surface forms a wall of the hammer head opening and flares outwardly towards the distal end of the tip.

5. (original) The crimping and cutting device of claim 2 wherein the first camming surface and the second camming surface abut flushly when the hammer head is at the distal end of the tip.

6. (original) The crimping and cutting device of claim 2 wherein the first camming surface does not abut the second camming surface when the hammer head is pulled proximally of the ferrule accepting opening.

7. (original) The crimping and cutting device of claim 1 wherein the tip further comprises an aperture between the distal end and the proximal end of the tip, the cutting edge located distally of the aperture.

8. (original) The crimping and cutting device of claim 1 wherein proximal movement of the hammer head within the tip causes the ferrule engaging edge of the hammer head to contact the cutting edge after the hammer head has past the ferrule accepting opening of the tip.

9. (original) The crimping and cutting device of claim 1 wherein the tip comprises a distal end outer diameter and a proximal end outer diameter, wherein the outer diameter of the distal end is greater than the outer diameter of the proximal end.

10. (original) The crimping and cutting device of claim 1 further comprising a handle assembly having a trigger, wherein activation of the trigger draws the hammer head proximally within the tip.

11. (original) The crimping and cutting device of claim 10 further comprising a safety button, wherein the trigger cannot be activated until the safety button is depressed.

12. (original) The crimping and cutting device of claim 10 further comprising an adjustment screw within the handle assembly, wherein a length of a central rod connecting the hammer head to the handle assembly is adjustable by the adjustment screw.

13. (original) The crimping and cutting device of claim 1 further comprising a tubular portion extending from the proximal end of the tip, the device

further comprising a suture loading assembly mounted on the tubular portion and slidable along the tubular portion.

14. (original) The crimping and cutting device of claim 1 wherein the suture loading assembly comprises a loop threadable through the ferrule accepting opening.

15. (withdrawn) A handle assembly for a surgical instrument, the handle assembly comprising:

a trigger member; and,

a safety button, wherein the trigger member is not movable until the safety button is depressed.

16. (withdrawn) The handle assembly of claim 15 further comprising a first side and a second side, the trigger member pivotable within the first side and the second side.

17. (withdrawn) The handle assembly of claim 16 wherein the safety button includes a pin having an engageable end and extending through either side of the handle assembly.

18. (withdrawn) The handle assembly of claim 17 wherein the safety button includes a first pin extending through the first side and a second pin extending through the second side.

19. (withdrawn) The handle assembly of claim 17 further comprising a spring surrounding the pin.

20. (withdrawn) The handle assembly of claim 17 wherein the safety button includes at least two ribs, a gap separating each pair of adjacent ribs.

21. (withdrawn) The handle assembly of claim 20 wherein the safety button includes a first side rib, a second side rib, and a middle rib, a first side gap located between the first side rib and the middle rib, and a second side gap located between the second side rib and the middle rib.

22. (withdrawn) The handle assembly of claim 20 wherein the trigger member includes a safety button engaging member, wherein, if the engageable end of the pin of the safety button is not depressed, then the safety button engaging member of the trigger will abut a rib when an attempt is made to move the trigger, and further wherein, if the engageable end of the pin of the safety button is depressed, then the safety button engaging member of the trigger will slide between a pair of adjacent ribs.

23. (withdrawn) The handle assembly of claim 22 wherein the safety button engaging member is hook shaped.

24. (withdrawn) The handle assembly of claim 18 wherein the safety button includes a first side rib adjacent the first pin, a second side rib adjacent the second pin, and a middle rib, a first side gap located between the first side rib and the middle rib, and a second side gap located between the second side rib and the middle rib.

25. (withdrawn) The handle assembly of claim 24 further comprising a first spring surrounding the first pin and a second spring surrounding the second pin.

26. (withdrawn) The handle assembly of claim 25 wherein the first side and the second side each include an opening for passing the first pin and the second pin, respectively, each opening including a pocket for seating the first spring and the second spring, each pocket having a greater diameter than a diameter of each opening.

27. (withdrawn) The handle assembly of claim 16 wherein the trigger includes a spring receiving member, the handle assembly further comprising a trigger

spring connected between the spring receiving member of the trigger and a protrusion within either the first side or the second side.

28. (withdrawn) The handle assembly of claim 16 further comprising an adjustment screw positioned between the first side and the second side, the adjustment screw for adjusting length of a rod extending from a distal end of the handle assembly.

29. (withdrawn) The handle assembly of claim 28 wherein the adjustment screw is only adjustable prior to securing the first side to the second side.

30. (withdrawn) A surgical instrument comprising:

a handle assembly;

a rod member extending from a distal end of the handle assembly; and,

an adjustment screw located within the handle assembly and upon a proximal end of the rod member, wherein length of the rod member outside of the handle assembly can be changed by the adjustment screw.

31. (withdrawn) The surgical instrument of claim 30 wherein a longitudinal axis of the rod member coincides with a longitudinal axis of the adjustment screw.

32. (withdrawn) The surgical instrument of claim 30 wherein the adjustment screw includes a bore through which a proximal end of the rod member is seated.

33. (withdrawn) The surgical instrument of claim 30 wherein the adjustment screw is contained within the handle assembly and not accessible after manufacture of the surgical instrument.

34. (withdrawn) The surgical instrument of claim 30 wherein the adjustment screw includes internal threads which engage with external threads on the rod member.

35. (withdrawn) A suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising:

a body,

an attaching member extending from the body for attaching the body to the surgical instrument; and,

a flexible loop extending from a distal end of the body.

36. (withdrawn) The suture loading assembly of claim 35 wherein the body includes a bore from which the loop extends.

37. (withdrawn) The suture loading assembly of claim 35 wherein the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument, wherein the attaching member is slidable along the cylindrical member of the surgical instrument.

38. (withdrawn) The suture loading assembly of claim 37 wherein an outer portion of each leg includes an indented area for forming a finger grip.

39. (withdrawn) The suture loading assembly of claim 35 further comprising a cap surrounding a portion of the body.

40. (withdrawn) The suture loading assembly of claim 39 wherein the cap includes finger grips.

41. (withdrawn) The suture loading assembly of claim 40 wherein the finger grips are indents in sides of the cap.

42. (withdrawn) The suture loading assembly of claim 39 wherein the cap includes openings for receiving the body and the attaching member.

43. (withdrawn) The suture loading assembly of claim 35 wherein the loop is made from wire.

44. (withdrawn) The suture loading assembly of claim 43 further comprising a plug inserted within a proximal end of the body for retaining the wire within the body.

45. (withdrawn) In combination, a suture securing instrument and a suture loading assembly,

the suture securing instrument comprising:

an elongated tubular portion having a distal end and a proximal end, the distal end including a ferrule accepting opening, the proximal end attached to a handle assembly;

the suture loading assembly comprising:

a body,

an attaching member extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument; and,

a flexible loop extending from a distal end of the body.

46. (withdrawn) The combination of claim 45 wherein the loop is threaded through the ferrule accepting opening.

47. (withdrawn) The combination of claim 45 wherein the attaching member is slidable along the tubular portion of the suture securing instrument.

48. (withdrawn) The combination of claim 47 wherein the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept the tubular portion of the suture securing instrument.

49. (withdrawn) The combination of claim 48 wherein an outer portion of each leg includes an indented area for providing a finger grip.

50. (withdrawn) The combination of claim 45 wherein the suture loading assembly further comprises a cap surrounding the body and attaching member, the cap extending past the tubular portion.

51. (withdrawn) The combination of claim 50 wherein the cap includes a pair of indents usable as finger grips.

52. (withdrawn) The combination of claim 45 wherein the suture securing instrument further comprises an aperture in the elongated tubular portion, the aperture located proximally of the ferrule accepting opening, the flexible loop threaded through the aperture prior to threading through the ferrule accepting opening.

53. (withdrawn) The combination of claim 52 further comprising a ferrule positioned in the ferrule accepting opening, the flexible loop threaded through the ferrule.

54. (withdrawn) The combination of claim 45 wherein the loop is made from a preformed wire bent into a diamond shape.

55. (Once amended) A method of securing suture material using a crimping and cutting device, the method comprising:

threading the suture material through a ferrule in the device;

moving a hammer head proximally through a tip of the device to crimp the ferrule;

continuing to move the hammer head proximally after the ferrule has been crimped entrapping the suture material within the ferrule;

abutting the hammer head against a generally stationary cutting edge within the tip, capturing the suture material therebetween; and,

applying pressure with the hammer head against the cutting edge until the suture material is cut.

56. (original) The method of claim 55 wherein moving the hammer head proximally comprises squeezing a trigger on a handle assembly of the crimping and cutting device.

57. (original) The method of claim 56 wherein a safety button is depressed on the handle assembly prior to squeezing the trigger.

58. (original) The method of claim 55 wherein threading the suture material through a ferrule comprises threading the suture material through a flexible loop extending from a distal end of the ferrule and pulling the flexible loop proximally until the suture material is threaded through the ferrule.

59. (original) The method of claim 55 wherein pulling the flexible loop proximally comprises sliding a suture loading assembly, which is mounted on a tubular portion of the cutting and crimping device and to which the flexible loop is attached, proximally along the tubular portion.

60. (withdrawn) A method of threading a suture securing instrument comprising:

mounting a suture loading assembly upon a tubular portion of the suture securing instrument; and,

threading a flexible loop extending from the suture loading assembly through a ferrule within a distal end of the suture loading assembly.

61. (withdrawn) The method of claim 60 further comprising inserting suture material through the flexible loop.

62. (withdrawn) The method of claim 61 further comprising pulling the flexible loop proximally until the suture material is threaded through the ferrule.

63. (withdrawn) The method of claim 62 wherein pulling the flexible loop proximally comprises sliding the suture loading assembly proximally along the tubular portion of the suture securing instrument.

64. (withdrawn) A kit for securing suture material within a body of a patient, the kit comprising:

a cutting and crimping device;

a ferrule loaded into the cutting and crimping device; and,

a suture loading assembly mounted on a tubular portion of the cutting and crimping device, a flexible loop extending from the suture loading assembly threaded through the ferrule.